

**Navajo Nation Human Research Review Board
Meeting Agenda**

DATE: January 16, 2018

TIME: 9:00 AM

PLACE: NDOH Conference Room, Window Rock, AZ

MEMBERS:

Mark C. Bauer - Scientific Education
Beverly Becenti-Pigman - Community
David Begay - Scientific Education
Rebecca Izzo-Manymules - Education
Ursula Knoki-Wilson - Nursing
Wallace McGilbert - Community
Raymond Reid, MD – Medicine
Kalvin White - Scientific Education

OLD BUSINESS:

- I. Meeting Call to Order:
- II. Roll Call:
 - Invocation
 - Introductions
- III. Review and Approval of Agenda:
- IV. Review of November 28, 2017 Meeting Minutes:

NEW BUSINESS:

- V. Quarterly Reports:
- VI. Serious Adverse Events (SAEs):
- VII. New Presentations:
- VIII. Returning Presentations:
- IX. Noon Hours Discussions:
- X. Manuscripts / Abstracts:
- XI. Announcements / Adjournment:

**Navajo Nation Human Research Review Board
IRB 1/16/2018 Meeting Agenda**

ADVERSE EVENT

1. NNR-17.282 PI: Hammit, Laura M.D.
A Study to Evaluate the Efficacy of Maternal Immunization with RSV F vaccine in Preventing RSV Lower Respiratory Tract Infection in Young Infants (RSV-M-302)

NEW PRESENTATION(S)

1. NNR-17.291T PI: Lance, Peter FRCP *TABLED ITEM Use Packet item from November 28, 2017 Meeting*
The Gut Microbiome of Navajo Healthy Volunteers
Reason on New Title
Description: Request Review and Approval of New Study
2. NNR-17.293T PI: Davis, Jonathan MAS, MA
Evaluating Geodesign as a Planning Framework for Navajo Nation Chapters
Reason on New Title
Description: Request Review and Approval of New Study
3. NNR-17.294T PI: Wangler, Valory MD
A Cultural Spiritual and Health Impact Assessment of Oil Drilling Operation in the Navajo Nation Area of Counselor, Torreon and Ojo Encino Chapters
Reason on New Title
Description: Request Review and Approval of New Study
4. NNR-17.295T PI: Greyeyes, Wendy Ph.D.
Building a Legacy of Cultural Grit and Survival: Dine' Youth and Elder Alliance
Reason on New Title
Description: Request Review and Approval of New Study

RETURNING PRESENTATION(S)

1. NNR-14.175 PI: Lombard, Kevin A. PhD
Where Health and Horticulture Intersect: A Navajo Wellness Collaboration
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering 1) May 1 - August 31, 2017; 2) September - December 2017 Period
2. NNR-14.177 PI: Duran, Bonnie G. Dr.PH
Tribal Colleges and Universities Behavioral Health Adaptation of an Evidence-Based Intervention
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering July - December 2017 period
3. NNR-11.349 PI: Bauer, Mark C. Ph.D
Navajo Gardening, Nutrition, and Community Wellness
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering: 1) October 17, 2016 - January 17, 2017, 2) January 17, 2017 - April 17, 2017; 3) April 17 - July 17, 2017; 4) July 17 - October 17, 2017.
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering April 2016 – April 2017 period

4. NNR-16.239 PI: Chee, Donald B.A.
Integrated HIV/AIDS & Substance Abuse Prevention Project for the Navajo Nation
Reason on Quarterly Review
Description: Requesting Review and Acceptance of Quarterly Reports covering: May 16 - August 16, 2017, August 16 - November 15, 2017 periods.
5. NNR-16.244 PI: Bauer, Mark C. Ph.D.
Identifying and Reinforcing Positive Behaviors among Dine' College Students
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Reports covering April 20 - July 19, 2017 and July 20 - October 19, 2017
6. NNR-17.277 PI: Moore, Kelly R M.D.
Stopping Gestational Diabetes in Daughters and Mothers - Phase 2
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering October 19, 2017 - January 19, 2018 period
7. NNR-17.281 PI: Garrison, Nanibaa' Ph.D.
Perspectives on Genetic Research in the Navajo Nation
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering August 15 - December 30, 2017 period
8. NNR-17.283T PI: Russell, Maureen Ph.D., OTR/L
Sleep Interventions for Caregivers and their Young Children in Part C Programs
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September 18 - December 19, 2017 period
9. NNR-17.284 PI: Yazzie, Delvin MPH
Navajo Nation Healthy Dine' Act: An Implementation Study
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering November 21, 2017 - January 16, 2018 period
10. NNR-02.094 PI: Knowler, William MD
Action for Health in Diabetes Look AHEAD
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 16, 2016 - October 16, 2017 period
Reason on Amendment
Description: Request Acceptance and Approval of Amendments to Protocol: 1) Headers and Footers changes to reflect Protocol 18, November 2017; 2) Page 1-14 Pittsburgh Fatigability, Loneliness and Resilience forms will be removed for the 2 year exam.
11. NNR-02.110 PI: Knowler, William MD
Diabetes Prevention Program Outcomes Study (DPPOS)
Reason on Amendment
Description: Request Acceptance and Approval of Amendment of 4.3 revisions: Definition of Retinopathy Outcomes; Definition of Neuropathy Outcomes; Procedures for obtaining surrogate consent, Secondary Research Questions, Outcomes Schedules, Informed Consent.
12. NNR-02.106 PI: Dabelea, Dana M.D.
SEARCH for Diabetes in Youth Study
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering October - December 2017 period
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering January 19, 2017 - January 19, 2018 period

- Reason on** Amendment
Description: Request Acceptance and Approval of Amendments: 1) Increase incentives to \$200, 2) Revised 2 Consent Forms.
- Reason on** Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering January 19, 2018 - January 19, 2019 period
13. NNR-03.121 PI: Bitsui, Natasha
- 2003 Navajo Youth Behavior Survey (YRBS)**
Reason on Change in Investigators
Description: Request Acceptance and Approval to Change in Principal Investigators from Ms. Natasha Bitsui to Ms. Sherry Brown as Lead P.I. and Ms. Philene Herrera as Co-P.I. Attached CV and Part 5 Certifications.
14. NNR-07.198 PI: Bennett, Kirsten, PhD, RD, LD ***TABLED ITEM Use Packet item from November 28, 2017 Meeting***
- Envision New Mexico Pediatric Overweight Learning Collaborative**
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering June 17 - September 16, 2017 period
- Reason on** Annual Report
Description: Request Acceptance and Approval of Annual Report covering January 16, 2016 - January 16, 2017 period
- Reason on** Continuation Request
Description: Request Acceptance and Approval of Request for Continuation covering January 16, 2018 - January 16, 2019 period
15. NNR-11.319 PI: Patten, Christi A. PhD
- Family Cancer Literacy to Promote Mammography Screening among Navajo Women**
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering May 23 - August 22, 2017 period
- Reason on** Annual Report
Description: Request Acceptance and Approval of Annual Report covering August 23, 2016 - August 23, 2017 period
16. NNR-11.342 PI: O'Connell, Joan M. Ph.D.
- Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data**
Reason on Amendment
Description: Request Acceptance and Approval of 2 Amendments to Protocol: 1) Additional Funding to completed Phase 2 analysis, and 2) clarification of officials titles and Project timeline to 6 years not 7 years.
17. NNR-11.348 PI: Francisco, Simental R B.S.
- Navajo Behavioral Risk Factor Surveillance Survey**
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering April - June 2017
- Reason on** Annual Report
Description: Request Acceptance and Approval of Annual Report cover July 24, 2016 - July 23, 2017 period
18. NNR-13.160 PI: Greyeyes, Wendy Ph.D.
- The Dependency of Sovereignty**
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly report covering August 20 - November 19, 2017 period
- Reason on** Dissertation Review
Description: Request Acceptance and Approval of Dissertation in candidacy for the Degree of Doctor of Philosophy.
19. NNR-16.251 PI: Frank, Daniel Z.
- 2003 Navajo Youth Behavior Survey (YRBS)**
Reason on Final Report - Dissertation
Description: Request Acceptance and Approval of Final Report - Dissertation in Partial Fulfillment of the Requirement for Degree of Doctor of Philosophy. 1- Dissemination Plan, 2- Amendment to Protocol, 3-Recommendation to Community, 4-Dissertation Slide for Dissertation.

20. NNR-17.273 PI: Dayle John, Kelsey B.A.
What can the Navajo Horse teach us about decolonizing education.
Reason on Final Report - Dissertation
Description: Request Acceptance and Approval of Dissertation
21. NNR-15.197 PI: DeAngelis, Margaret PhD. *TABLED ITEM Use Packet item from December 19, 2017 Meeting*
Retinal Screening Program UNHS and Moran Eye Center Collaboration.
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering October 18, 2016 - October 18, 2017 period
Reason on Continuation Request
Description: Request Acceptance and Approval of Request for Continuation covering October 18, 2017 - October 18, 2018 period
22. NNR-15.212 PI: Solomon, Mark G. *TABLED ITEM Use Packet item from December 19, 2017 Meeting*
2015 Safety Belt Use Estimates for the Indian Nations.
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering October 1 - December 31, 2017 period
Reason on Annual Report
Description: Request Acceptance and Approval of 2017 Annual Report covering July 21, 2016 - July 21, 2017 period
23. NNR-15.223 PI: Richards, Jennifer MPH
Formative Research to Inform the Development of an Intergenerational Strengths-Based Program for American Indian Girls as they Transition to Adulthood.
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering December 15, 2016 - December 15, 2017 period
Reason on Amendment
Description: Request Acceptance and Approval of Amendments: 1) Revised Data Collection Instruments; 2) Revised Consent Form (IDI); 3) Revised Recruitment Script.
24. NNR-16.234 PI: Chief, Karletta Ph.D.
To Litso, the water is Yellow: Investigating short term exposure and risk perception of Navajo communities to the Gold King Mine toxic spill
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering January 19, 2017 - January 19, 2018 period
Reason on (Other)
Description: Request Acceptance and Approval of Power Point Presentation "Top Concerns from Focus Groups" for Community Dissemination
Reason on Quarterly Review
Description: Request Acceptance and Approval of Winter 2017/2018 New Letter for Community Dissemination
Reason on Abstract Submission
Description: Request Acceptance and Approval of Abstract - Dissertation Proposal for Yoshire Ornelas Van Hornes "Exposures and Health Risks for the Dine Communities Impacted by the Gold King Mine Spill" Attachments: University of Arizona IRB Approval Letter, Dissertation Approval Letter.
25. NNR-16.257 PI: Lombard, Kevin A. PhD
Engaging Family and School in Navajo Gardening for Health
Reason on Quarterly Review
Description: Request Review and Acceptance of Quarterly Report covering September - December 2017 period
Reason on Amendment
Description: Request Acceptance and Approval of Fred Hutchinson Modification for Qualitative Interview Guide.

26. NNR-17.286 PI: Whyte, Ayn N. MS
American Indian/Alaska Native Health Equity Initiative
Reason on Amendment
Description: Request Acceptance and Approval of Amendments to Protocol: 1) Focus Group, 2) Self-administered scale, 3) Environmental scan.
27. NNR-11.332 PI: Speakman, Kristen MA. MPH
Evaluation of an Edible School Garden Program; Evaluation of the Feast for the Future Community Visioning Program.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering February 21, 2018 - February 21, 2019 period
28. NNR-16.238 PI: Lammitt, Laura M.D.
Active Bacterial Surveillance for Staphylococcus aureus on the Navajo and White Mountain Apache Reservations.
Reason on Continuation Request
Description: Request Acceptance and Approval of Continuation Request covering February 16, 2018 - February 16, 2019 period
29. NNR-15.201 PI: Bauer, Mark PhD.
Reason on Quarterly Review
Description: Request Review and Acceptance of Annual Report covering: 1) December 17, 2016 - March 17, 2017;
2) March 17 - June 17, 2017; 3) June 17 - September 17, 2017; 4) September 17 - December 17, 2017 periods
Reason on Annual Report
Description: Request Acceptance and Approval of Annual Report covering March 17, 2016 – March 2017 period

IX. Noon Hours Discussions:

X. Manuscripts / Abstracts: 1) The Early Navajo Pastoral Landscape (Ad 1626-1775): Incipient Indigenous Pastoralism in (Peri) Colonial New Mexico – *James W. Campbell, MA, PhD. Candidate*; 2) Utah State University High School/Middle School Spatial Ability Research – *Wade Goodridge PhD. Candidate*

XI. Announcements / Adjournment

Last page and end of Agenda

Report Date: Wednesday, January 03, 2018